0615 '00 SEP 26 A9:15

September 25, 2000

VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 95P-0054; Comments In Support Of Marketing Restrictions For Use Of Mifepristone As An Abortifacient

Dear Sir or Madam:

As an attorney who specializes in "food and drug law" and regulatory counseling for companies that market FDA-regulated products, I submit these comments on my own behalf, in support of FDA's decision to require certain marketing restrictions for approval of the new drug application for mifepristone for use as an abortifacient.

It has been reported that, during its review of the mifepristone NDA, FDA has considered requiring certain risk management activities related to the drug's approval. In particular, it has been reported that FDA has proposed a national registry for doctors who prescribe the drug, a requirement that doctors have admitting privileges at a nearby hospital and training in surgical abortions, and a post-approval study of women who use the drug in an effort to continue to monitor the drug's safety.

Given FDA's statutory authority for, and long history of, requiring risk management activities (especially post-approval studies) for drug products with risky safety profiles, the agency's proposed restrictions on the use of mifepristone are eminently reasonable and based on sound science. Both the extent and nature of the adverse events associated with chemical abortion support the agency's actions. Furthermore, precedent supports the agency in this case, in light of the fact that FDA has required similar marketing restrictions for other approved drugs that carry serious risks to patient health, whether maternal or fetal; for example, thalidomide and isotretinoin. Clearly, the manufacturer of mifepristone should be held to the same scientific standards as other drug manufacturers with respect to post-approval management and supervision of an approved prescription drug.

Thank you for your consideration of these comments.

Respectfully submitted,

Rebecca L. Dandeker

Rebecca L. Dandeker, Esq.
McKenna & Cuneo, L.L.P.
Washington, D.C.

95P-0054

C 315

FedEx interNetShip Label7918 5771 3368

From: CAROL LYN BROWN (202)496-7613
MCKENNA & CUNEO, L.L.P
1900 K STREET, N.W

WASHINGTON, DC, 20006

SHIPPER'S FEDEX ACCOUNT #

FedEx.

To: Dockets Management Branch (202)496-7568
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD, 20852

SHIP DATE: 25SEP00
WEIGHT: 1 LBS

Ref: 100000001

DELIVERY ADDRESS

TRK # 7918 5771 3368 FORM 0201

PRIORITY OVERNIGHT

TUE
AA
Deliver by:
26SEP00

20852-MD-US

IAD
19 GAIA